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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/804,103 | 03/19/2004 | Kenji Otsuka | 396.43502X00 | 7099 |

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| EXAMINER | |
|---|---|
| SODERQUIST, ARLEN | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1797 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/804,103 | OTSUKA ET AL. | |
| | Examiner | Art Unit | |
| | Arlen Soderquist | 1797 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11-5-2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 5-7 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The type of metal compound does not change the structure or composition of the detecting agent since it is not recited as an element of the detecting agent.

2. Claim 15 is objected to because of the following informalities: at the end of the claim "molecular structure" was apparently intended. Appropriate correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of Albero, Ershova or Morosanova (Fresenius' Journal of Analytical Chemistry 1998, hereinafter referred to as Morosanova '98 and Journal of Analytical Chemistry 2000, hereinafter referred to as Morosanova '00).

In the paper Albero presents a determination of zinc (II) in pharmaceuticals based on a flow-through bulk optode. A method based on flow injection (FI), was applied for the determination of Zn (II) using a flow-through bulk optode membrane that incorporates 1-(2-pyridylazo)-2-naphthol in a plasticized poly (vinyl chloride) membrane entrapped in a cellulose support (anticipatory of the structure). See page 781 for the preparation of the optode. The calibration graph plotting the reflectance at 562 nm vs. [Zn (II)] was linear in the range 0.16-3.27 mg l-1 ($2.5\times10^{-6}$-$5\times10^{-5}$ M) with a detection limit of 0.10 mg l-1. The variation coefficients of the sensor response for 0.33 mg l-1 of Zn (II) were ±0.11% for consecutive measurements (n=10), ±0.19% between days (n=5) and ±0.22% between different membranes (n=6). The sensor can be readily regenerated with the same acetic/acetate carrier of pH 3.9. The FI method proposed was applied to the determination of zinc (II) in pharmaceuticals.

In the paper Ershova presents diffuse reflection spectroscopy of indium sorbates with immobilized heterocyclic azo compounds. Diffuse reflection was used for the direct

determination of indium after preconconcentration on a solid support. The best conditions were found for sorption of indium complexes with 1-(2-pyridylazo)-2-naphthol (PAN), 4-(2-pyridylazo)resorcinol (PAR) and 2-(5-bromo-2-pyridylazo)-5-diethylaminophenol (5-Br-PADAP) immobilized on a silica gel Silochrom S-120 (anticipatory of the structure). Optical characteristics of the complexes in solutions and on sorbent are practically the same for the variations of the Gurevich-Kubelka-Munk function, color lightness and chromaticity coordinates. The linear solutions of variations of these quantities with the indium contents were determined. 4 μg indium could be concentrated on 0.3 g modified silica gel with immobilized 5-Br-PADAP from a sample volume of 200 mL with an enrichment factor exceeding 600.

In the paper Morosanova '98 teaches new sorbents and indicator powders for preconcentration and determination of trace metals in liquid samples. Two approaches to immobilize complex-forming analytical reagents (PAN, PAR, xylenol orange, bromobenzthiazo, crystal violet, Cadion, and sulfochlorophenolazorhodanine) for the preparation of new sorbents and indicator powders are suggested: online coating of reversed-phase silica gel by reagents or doping of porous sol-gel silica with reagents (anticipatory of the structure). The retention of Ag, Cd, Cu(II), Co(II), Fe(III), Mn(II), Pb, and Zn by the sorbents was investigated. Quantitative sorption and desorption conditions were optimized. Procedures for the determination of Cd, Cu(II), Fe(III), Pb, and Zn with flame atomic absorption, spectrophotometric, and diffusion scattering spectrometric detection were elaborated. Detection limits for Cd, Cu(II), Fe(III), Pb, and Zn were 3, 6, 5, 40, and 1 μg/L, respectively. The procedures were used for the analysis of various real samples, e.g., natural and wastewaters, and food.

In the paper Morosanova '00 teaches xerogels doped with 1-(2-pyridylazo)-2-naphthol and xylenol orange and indicator tubes and indicator powders (anticipatory of the structure) for determining copper(II) and iron(III) in solution. $SiO_2$-based xerogels doped with 1-(2-pyridylazo)-2-naphthol and Xylenol Orange were prepared. The xerogels differ in the specific surface and the reagent concentration. Modified xerogels were used as indicator powders for determining Cu(II) and Fe(III) using indicator tubes. The effects of the reagent concentration in the indicator powder and its specific surface on the length of the colored zone were studied. Indicator tubes were developed for determining 0.3-300.0 mg/L Cu(II) and 1.0-120.0 mg/L

Fe(III) in solutions. The results of determining Cu(II) in plant mineral food and Fe(III) in natural waters and ashed milk powder are presented.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakajima (JP 11-264816 in view of Morosanova '98 or Morosanova '00 as explained above. In the published application Nakajima teaches a detecting agent for organometallic compounds. The detecting agent is intended to detect an organometallic compound such as a metal alkyl compound, a metal alkoxide or the like as a single component, by using at least one out of Xylenol Orange and copper (II) chloride as a discoloring component. One out of Xylenol Orange and copper (II) chloride as discoloring components for the detecting agent is normally used singly. The Xylenol Orange displays yellow at a pH of 6 or lower, it becomes an aqueous solution in purplish red at a pH of 6 or higher, it is acid, and it becomes red when it generates a chelate compound with metal ions. On the other hand, the copper (II) chloride is a crystal in ocher, and it is discolored to be gray when it comes into contact with an organometallic compound. When both are used as the detecting agent, they can be used as they are as a powder or they can be used so as to be molded to be a proper shape. It is preferable that both are dissolved in a solvent such as water, alcohol or the like, and that they are immersed in a carrier so as to be carried. As the carrier, silica gel, alumina and the like are enumerated, it is preferably colorless or white, and the silica gel is most suitable. The translation of paragraph [0011] give an example in which Xylenol Orange on a

silica gel carrier is used to detect organometallic compounds. Paragraph [0012] gives the results in table form and teaches that the color changes in about 5 minutes. Nakajima does not teach other indicators on a carrier for the same purpose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the other pyridylazo dyes taught by Morosanova '98 or Morosanova '00 in the Nakajima method because of their known use as carrier supported analytical reagents for metals and their use in situations that are similar to the Xylenol Orange as taught by both Morosanova '98 and Morosanova '00 (Xylenol Orange is one of the indicators that Morosanova '98 or Morosanova '00 teach in addition to the pyridylazo dyes).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art is related to pyridylazo compounds and their use in the analysis of metals. .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Arlen Soderquist
Primary Examiner
Art Unit 1797